

REMARKS

Applicants thank the Examiner for the detailed Office Action dated May 3, 2006. Applicants respectfully request reconsideration of the present application in view of the reasons that follow.

Claims 1-42 were previously pending in the application. Claim 41 is requested to be cancelled without prejudice or disclaimer. Claims 1, 4, 15-16, 19-20, 22-23, 25-26, 28-31, 34, 37, 39-40, and 42 are currently being amended. Claims 43-46 are being added. After amending the claims as set forth above, claims 1-40 and 42-46 are now pending in this application.

For simplicity and clarity purposes in responding to the Office Action, Applicants' remarks are primarily focused on the rejections of the independent claims (*i.e.*, claims 1, 15, 25, 28, 31, 34, 37, 41, and 42) outlined in the Office Action with the understanding that the claims that depend from the independent claims are patentable for at least the same reasons (and in most cases other reasons) that the independent claims are patentable. Applicants expressly reserve the right to argue the patentability of the dependent claims separately in any future proceedings.

Claim Rejections – 35 U.S.C. § 112 ¶2

On pages 2 and 5 of the Office Action, claims 1-14 and 34-41 were rejected under 35 U.S.C. § 112 ¶2 as being unpatentable for failing to particularly point out and distinctly claim the subject matter which the Applicants regard as the invention. In particular, the Examiner objected to the use of “open rectangle” and questioned what the term “rectangular dimensions” refers to in independent claims 1, 34, 37, and 41. Initially, Applicants note that independent claim 41 has been cancelled and independent claim 37 has been amended to remove the “open rectangle” terminology.

With regard to independent claims 1 and 34, Applicants have amended these claims to remove the “rectangular dimensions” terminology. In the Office Action, the Examiner asserted that it is not certain what constitutes a rectangle that is open and that the term “open rectangle” must be defined within the claim. Applicants respectfully submit that the specification makes clear what is being referred to by the term “open rectangle.” The specification states on page 5 that the term “‘Open,’ when used as an adjective to modify a shape means without any folds or modifications.” Also, there is no legal principle that requires the term “open rectangle” to be defined within the claim itself. To the contrary, MPEP § 608.01(o) explains that “[t]he meaning of every term used in any of the claims should be apparent from the descriptive portion of the specification . . .” and “[a] term used in the claims may be given a special meaning in the description.”

Applicants respectfully submit that the rejected claims particularly point out and distinctly claim the subject matter in compliance with 35 U.S.C. § 112 ¶ 2. Accordingly, Applicants respectfully request that the rejection be withdrawn.

Claim Rejections – 35 U.S.C. § 102

Independent Claim 1

On pages 2 and 3 of the Office Action, independent claim 1 and various dependent claims were rejected under 35 U.S.C. § 102(b) as being unpatentable over either U.S. Patent No. 6,425,924 (Rousseau) or U.S. Patent No. 5,662,681 (Nash et al. I). Applicants respectfully traverse the rejection. Neither Rousseau nor Nash et al. I identically disclose the subject matter recited in independent claim 1.

Applicants respectfully submit that Rousseau does not disclose a “tissue puncture closure device” including, among other elements, a “carrier tube” and a “sealing plug” “positioned in the carrier tube,” as recited in independent claim 1. The structure that the Examiner is interpreting as the “sealing plug” in Rousseau is not positioned inside a “carrier tube.”

Applicants also respectfully submit that Nash et al. I does not disclose a “tissue puncture closure device” including, among other elements, a “sealing plug” where the “sealing plug comprises a shape that when open has a higher surface area-to-volume ratio than an open rectangle,” as recited in independent claim 1. Applicants respectfully submit that when the plug 30 shown in Nash et al. I is open it is an open rectangle. Therefore, the plug 30 does not comprise a shape that when open has a higher surface-area-to-volume ratio than an open rectangle.

For the above reasons, Applicants respectfully submit that independent claim 1 and the claims which are dependent thereon are not anticipated by either Rousseau or Nash et al. I under 35 U.S.C. § 102(b) and are patentable.

Independent Claim 15

On pages 2 and 3 of the Office Action, independent claim 15 and various dependent claims were rejected under 35 U.S.C. § 102(b) as being unpatentable over either Rousseau, Nash et al. I, or U.S. Patent No. 5,312,435 (Nash et al. II). Applicants respectfully traverse the rejection. Neither Rousseau, Nash et al. I, nor Nash et al. II identically disclose the subject matter recited in independent claim 15.

Applicants respectfully submit that Rousseau does not disclose a “tissue puncture sealing device” including, among other elements, an “internal component configured to be positioned

against an internal wall of a bodily lumen,” and an “external component configured to be positioned external to the lumen,” where “the external component is operatively connected to the internal component by a filament configured to compress and hold the internal and external components together to prevent fluid from passing through a puncture in the bodily lumen,” as recited in independent claim 15. Applicants submit that what the Examiner is interpreting as the internal component (the lower conical member 14) and the external component (the upper conical member 12) in the “hernia repair prosthesis” shown in Rousseau do not prevent fluid from passing through a puncture in the bodily lumen because the hernia repair prosthesis uses a mesh material that is porous. (Rousseau, col. 4, lines 41-44; Figs. 1-4.)

Applicants also respectfully submit that neither Nash et al. I nor Nash et al. II disclose a “tissue puncture sealing device” including, among other elements, an “internal component configured to be positioned against an internal wall of a bodily lumen,” and an “external component configured to be positioned external to the lumen, the external component being folded so that one portion of the external component is in contact with another portion of the external component” where “the tissue puncture sealing device is in an undeployed configuration,” as recited in independent claim 15. With regard to Nash et al. I, Applicants note that when the closure device is in the undeployed configuration (see Fig. 1), the plug 30 is not folded. With regard to Nash et al. II, the plug member 28 is not shown as being folded when the closure device is in an undeployed configuration. The portions of Nash et al. II referred to in the Office Action show the closure device after it has been deployed.

For the above reasons, Applicants respectfully submit that independent claim 15 and the claims which are dependent thereon are not anticipated by Rousseau, Nash et al I., or Nash et al. II under 35 U.S.C. § 102(b) and are patentable.

Independent Claim 25

On page 2 of the Office Action, independent claim 25 was rejected under 35 U.S.C. § 102(b) as being unpatentable over Rousseau. Applicants respectfully traverse the rejection. Rousseau does not identically disclose the subject matter recited in independent claim 25.

Applicants respectfully submit that Rousseau does not show an “internal tissue puncture closure device” including, among other elements, an “anchor,” a “filament threaded through the anchor,” and a “sealing plug attached to the anchor by the filament,” where the “sealing plug comprises two cross members each of which includes a plurality of holes which extend therethrough,” and where the “filament extends through the plurality of holes in each of the two cross members,” as recited in independent claim 25. Specifically, Rousseau does not include cross members that each have a plurality of holes in them. What the Examiner appears to be interpreting as the cross members – *i.e.*, the filamentous members in the mesh – do not each have a plurality of holes in them. They may define a plurality of holes when assembled in the mesh pattern, but they do not themselves have holes in them. Accordingly, Applicants respectfully submit that independent claim 25 is not anticipated by the cited reference and is patentable.

Independent Claim 28

On page 2 of the Office Action, independent claim 28 was rejected under 35 U.S.C. § 102(b) as being unpatentable over Rousseau. Applicants respectfully traverse the rejection. Rousseau does not identically disclose the subject matter recited in independent claim 28.

Applicants respectfully submit that Rousseau does not show a “tissue puncture sealing device” including, among other elements, a “filament,” an “anchor,” and a “flexible sealing plug disposed proximal of the anchor, the flexible sealing plug including a first plurality of openings and a second plurality of openings,” where the “filament passes through the first plurality of openings, through the anchor, and back through the second plurality of openings,” as recited in independent claim 28. Applicants submit that what the Examiner interprets as being the sealing plug in Rousseau – the upper conical member 14 – does not include a first plurality of openings and a second plurality of openings through which the suture 22 passes. Rather, the suture 22 only passes through a single opening (rather than a first plurality of openings as recited in claim 28) prior to passing through what the Examiner is interpreting as the anchor – the lower conical member 14 – and only passes through a single opening (rather than a second plurality of openings as recited in claim 28) after passing through the lower conical member 14. (Rousseau, Fig. 1.). Accordingly, Applicants respectfully submit that independent claim 28 is not anticipated by the cited reference and is patentable.

Independent Claim 31

On page 4 of the Office Action, independent claim 31 was rejected under 35 U.S.C. § 102(e) as being unpatentable over U.S. Patent No. 6,508,828 (Akerfeldt et al.). Applicants respectfully traverse the rejection. Akerfeldt et al. does not identically disclose the subject matter recited in independent claim 31.

Applicants respectfully submit that Akerfeldt et al. does not show a “tissue puncture closure device” including, among other elements, a “carrier tube having first and second ends,” an “anchor disposed outside of the carrier tube at the first end thereof,” and a “sealing plug

disposed inside the carrier tube at the first end thereof,” where the “sealing plug is folded at least once” and “the tissue puncture closure device is in an undeployed configuration,” as recited in independent claim 31. Specifically, Akerfeldt et al. does not show what the Examiner is interpreting as the anchor (*i.e.*, the first sealing member 2) disposed outside of the tube 24 and the sealing member (*i.e.*, the second sealing member 6) disposed inside the tube 24 when the closure device is in an undeployed configuration. The closure device in Akerfeldt et al. is deployed when the first sealing member 2 is shown outside of the tube 24 and the second sealing member 6 is shown inside the tube 24 (Akerfeldt et al., Figs. 11-13.) Accordingly, Applicants respectfully submit that independent claim 31 is not anticipated by the cited reference and is patentable.

Independent Claim 34

On page 4 of the Office Action, independent claim 34 was rejected under 35 U.S.C. § 102(e) as being unpatentable over Akerfeldt et al.. Applicants respectfully traverse the rejection. Akerfeldt et al. does not identically disclose the subject matter recited in independent claim 34.

Applicants respectfully submit that Akerfeldt et al. does not show a “tissue puncture closure assembly” including, among other elements, an “insertion sheath receptive of a closure device,” the “closure device” which includes a “carrier tube,” a “filament,” an “anchor,” and a “sealing plug disposed inside the carrier tube,” as recited in independent claim 34. In the Office Action, the Examiner is taking the position that the introducer 24 in Akerfeldt et al. is the carrier tube recited in claim 34. However, Applicants note that claim 34 also recites an “insertion sheath.” The Examiner has failed to explain what constitutes the insertion sheath since the introducer 24 is being interpreted as the carrier tube. Applicants note that the pusher 22 in

Akerfeldt et al. cannot be the carrier tube because claim 34 recites that the sealing plug is disposed inside the carrier tube and the second sealing member 6 in Akerfeldt et al. is not shown as being disposed inside the pusher 22. Applicants respectfully submit that Akerfeldt et al. does not show both a carrier tube and insertion sheath as recited in claim 34. Accordingly, Applicants respectfully submit that independent claim 34 is not anticipated by the cited reference and is patentable.

Independent Claims 37 and 42

On page 4 of the Office Action, independent claims 37 and 42 and various dependent claims were rejected under 35 U.S.C. § 102(e) as being unpatentable over Akerfeldt et al. Applicants respectfully traverse the rejection. Akerfeldt et al. does not identically disclose the subject matter recited in independent claims 37 and 42.

With regard to independent claim 37, Applicants respectfully submit that Akerfeldt et al. does not show a “method of sealing an internal tissue puncture” including, among other steps, “inserting a closure device into the internal tissue puncture, the closure device being in an undeployed configuration and including an anchor and a sealing plug, the sealing plug being folded so that one portion of the sealing plug is in contact with another portion of the sealing plug,” “deploying the anchor,” “filling the internal tissue puncture with the sealing plug,” and “compressing the sealing plug and the anchor across the internal tissue puncture,” as recited in independent claim 37. More specifically, Akerfeldt et al. does not show what the Examiner is interpreting as the sealing plug – *i.e.*, the second sealing member 6 – as being folded so that one portion of the sealing plug is in contact with another portion of the sealing plug. Rather, the

sealing members shown in Akerfeldt et al. appear to wrap up around the sides of the introducer so that no two portions of the sealing members contact each other. (Akerfeldt et al., Fig. 18.)

With regard to independent claim 42, Applicants respectfully submit that Akerfeldt et al. does not show a “tissue puncture closure device” including, among other elements, a “carrier tube,” an “anchor,” and a “sealing plug,” where the “sealing plug is folded at least once so that one portion of the sealing plug is in contact with another portion of the sealing plug,” as recited in independent claim 42. As explained in the previous paragraph, the second sealing member 6 in Akerfeldt et al. is not folded so that one portion of the sealing plug is in contact with another portion of the sealing plug.

For these reasons, Applicants respectfully submit that independent claims 37 and 42 and the various claims which depend therefrom are not anticipated by the cited reference and are patentable.

New Claims

Applicants have added new claims 43-46, of which claims 43 and 45 are in independent format. These new claims more comprehensively, in combination with other existing and future claims, recite the claimed invention. Applicants submit that new claims 43-46 are patentable over the cited references.

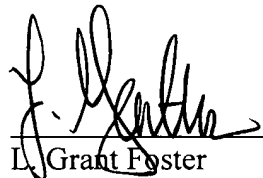
Allowable Subject Matter

Applicants respectfully put the Examiner and all others on notice that all arguments, representations, and/or amendments contained herein are only applicable to the present patent application and should not be considered when evaluating any other patent or patent application including any patents or patent applications which claim priority to this patent application and/or

any patents or patent applications to which priority is claimed by this patent application. Applicants thank the Examiner for indicating that claims 21, 23-24, 26-27, 29-30, and 32-33 contain allowable subject matter. Applicants respectfully submit that the present Application is in condition for allowance. Applicants request reconsideration and allowance of the pending claims. Applicants invite the Examiner to contact the undersigned by telephone if there remain unresolved matters to expedite the prosecution of the present application.

Respectfully submitted,

Date: 3 August 2006



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